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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,548	09/30/2005	Kunio Kamata	279057US0PCT	3923

22850 7590 03/03/2009

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
03/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/551,548	KAMATA ET AL.	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13,20 and 22* is/are rejected.

7)☒ Claim(s) *14-19,21 and 23-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The response and amendment filed in on January 14, 2009 have been acknowledged. Claims 10, 14, 15, 20, 22 have been amended. New claims 24-30 have been added. Claims 10-30 are pending and considered by the examiner.

Claim Rejections - 35 USC § 112 (Withdrawn)

1. The rejection of claim 22 under 35 U.S.C. 112, first paragraph for the enablement rejection has been withdrawn necessitated by Applicants' amendment.

2. The rejection of claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn necessitated by Applicants' amendment.

3. The rejection of claims 20 and 22 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps has been withdrawn necessitated by Applicants' amendment.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. (Maintained) Claims 10-13, and 20 are still under 35 U.S.C. 102(b) as being anticipated by Hardy et al. (Virology, 1996, Vol. 217, pp. 252-261) on the same ground as stated in the previous office action.

6. In the response, Applicants traverse the rejection and submit that claim 10 has been amended by adding a limitation of the composition comprising a norovirus or Sapovirus, and the butter at pH as 9.0-10.0, whereas the cited reference described that the high pH antibody coating butter is removed after an overnight incubation followed by a subsquential blocking and washing steps prior to the virus specimen addition. Therefore, the cited reference does not teach the limitation as claims amended.

7. Applicants' argument has been respectfully considered; however, it is not persuasive to withdraw the rejection, because the immunological electron microscope (IEM) assay taught by Hardy et al. still reads on the claimed composition. Hardy et al. teach that the assay is performed by adding anti-norovirus antibody into a sample comprising the recombinant Norwalk virus particles diluted in an alkaline 10 mM Tris buffer at pH 9.0. This is considered to be a composition comprising the norovirus and anti0norovirus antibody in a buffer at pH 9.0 that meets the limitation of the claims 10, 11, 12. Regarding the citation that the antibody may be mobilized to a solid support or labeled, because this limitation is cited as an option, a reasonable interpretation of the broadest scope of claim reads on that antibody with or without mobilized and labeled, the non-immobilized and unlabeled anti-norovirus antibody taught by Hardy still meets the limitation of claims 10, 11, 12. Therefore, the rejection of claims 1-12 are maintained.
8.

9. (Withdrawn) The rejection of Claims 10, 13, 14, 16 and 20-21 under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al. (J. Med. Virol, 2000, Vol. 62, pp.233-238) or Hale et al. (Clinical and Diagnostic Virology 1996, Vol. 5, pp. 27-35) has been removed in view of claims amendment and the argument.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. (Withdrawn) The rejection of claims 10, 13, 15-16, 20-21 under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. (J. Med. Virol, 2000, Vol. 62, pp.233-238) and Kitamoto et al. (J. Clin. Micro. 2002, Vol. 40, No. 7, pp. 2459-2465) has been removed necessitated by Applicants' amendment and inv view of the persuasive argument.

12. (Maintained) Claims 10-13, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardy et al. (Virology, 1996, Vol. 217, pp. 252-261) and Kitamoto et al. (J.

Clin. Micro. 2002, Vol. 40, No. 7, pp. 2459-2465). The rejection of claims 22-23 are necessitated by Applicants' amendment for claim 22.

13. In the response, Applicants assert that Hardy and Kitamoto, as shown above do not disclose a composition prepared in a high pH (9:0 to 10:0) buffer that contains virus specimen and antibody together. The stool samples taught by Hardy et al are prepared in PBS (lower pH). Moreover, the reference does not suggest or provide a reasonable expectation of success for the superior antigenic sensitivity obtained by specimen preparation at a higher pH as disclosed in the paragraph bridging pages 4-5 of the specification. Accordingly, this rejection cannot be sustained.

14. Applicants' argument has been respectfully considered; however, it is not persuasive. The bridge of page 4-5 described that preparing the specimen comprising norovirus or sapovirus with buffer having pH of 9.0 to 10.0, such that the virus particle are disintegrated to thereby allow epitope within the virus particle to be exposed, resulting in enhancement in antigen-antibody reaction. However, the immunological electron microscope (IEM) assay taught by Hardy et al. is performed by the same methodology, i.e. adding anti-norovirus antibody into a sample comprising the recombinant Norwalk virus particles diluted in an alkaline 10 mM Tris buffer at pH 9.0.

15. Moreover, prior to the current Application was filed, the anti-Sapovirus antibodies such as SV68 and SV137 had been isolated and identified to specifically recognize Sapporo virus as evidenced by Kitamoto et al. Kitamoto et al. also teach that the anti-Sapovirus antibodies can only recognize Sapovirus and anti-Norovirus can only recognize Norovirus, these two kinds of antibodies are not cross-reactive each other.

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references by using the anti-norovirus antibody to recognize norovirus or using the anti-sapovirus antibody to recognize Sapovirus respectively in the diagnosis assay taught by Hardy et al. with a reasonable expectation of success.

17. The case law of KSR concludes that Ordinary Innovation is obvious. In KSR, the Court ruled that teaching, suggestion or motivation does not need to be explicit and courts can take into account the inferences and creative steps that a person of ordinary skill in the art may employ.

"A person of ordinary skill is also *a* person *of ordinary creativity*, not an automaton." Furthermore, the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

18. Hence, absence of an unexpected result to the contrary, the claimed invention as a whole is prima facie obvious absence unexpected results.

New Ground of Rejection

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

19. In the instant case, claim 12 fails to further limit claim 10, because the "Good's Buffer accepted in the art is the buffer has pH 6.0-8.0 in light of the disclosure by SIGM-ALDRICH catalog published on line (Search on Feb. 25, 2009); which fails to meets the limitation of independent claim 10 that claim 12 depends on.

20. Claim 12 is also vague for failing to define what the structural and functional limitations of the antibody are, because it is not clear if the claimed antibody is immobilized and labeled or not immobilized and labeled.

Conclusion

Claims 14-19, 21 and 23-30 are deemed free of prior art, given failure of the prior art to teach or reasonably suggest an ELISA for detecting norovirus or saporovirus need be performed with incubating the labeled and unlabeled anti-norovirus or the labeled and non-labeled anti-sapovirus together with the virus in the reaction mixture, wherein the reaction mixture used as a specimen diluents have a high pH of 9.0-10.0 and also comprises other animal globulin, a water soluble polymer, and surfactant for reducing the non-specific binding.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/ Examiner, Art Unit 1648